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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,124	02/04/2002	Shigeru Oita	02070/HG	5979

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/067,124

Applicant(s)

OITA, SHIGERU

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,22-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1, 4-8,22-23 are pending.

New claim 23 has been submitted.

Claim 1,4, and 8 have been amended.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Response to Arguments*

2. Applicant's arguments with respect to claims 1,4-8,22-23, filed April 21, 2004 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4,6-7 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Vernon et al (WO96/41608).

Vernon et al disclose the instantly claimed composition that comprises:

a) 1 mM EDTA (see Example 2, lines 8-13 and page 6, Figure 4 narrative lines 10-25, especially “PT in phosphate buffer (ph 6.9, 1mM EDTA)”) together with

b) *Pyricularia thionin* within the concentration range of 1 µg/ml to 150 µg/ml , wherein the concentration is about 5.28 µg/ml (see Example 2, line 8 “PT at 10<sup>-3</sup> M: the 1 mM concentration of PT is defined by about 5.28 grams/mole/liter (molecular weight given at page 13, lines 6-7) which equates to 5.28 µg/ml for a 1 mM solution of PT in 1 mM

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EDTA) . The disclosed thionin evidences homology with both alpha-type and beta-type thionins (see page 13, section 5.4.2 and Table 1) in light of the fact that the amino acid sequence of the disclosed thionin shares homology with cereal thionins by containing 8 conserved cysteine residues (see Table 1, page 13, alpha -1, alpha-2 and beta thionins shown to evidence homology).

The reference anticipates the instantly claimed compositions.

5. Claims 1, 4-8 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (effective filing date October 11, 2000) as evidenced by Oita et al (2000).  
pg Pub 2004/0005682A1

Chen et al disclose the instantly claimed composition that comprises:

- a) 0.1 mM EDTA (see page 9, paragraph [0093]), the solution containing sodium [50 mM NaCl, 0093] together with
- b) an thionin within the concentration range of 1 µg to 150 µg (solutions produced comprise a range of concentrations from 0.005% to 10%, see page 5, [0045-0046]) , wherein the concentration applied to a series of filter discs included 1,2,3,6,10,20, 40 ug of VrCRPΔsp [see page 9, [0093]], a type of thionin (see abstract; page 1 [003]; page 3, [0025]). The thionin disclosed comprises an amino acid sequence with 8 cysteines (see SEQ ID NO 1), thus showing homology with alpha and beta type thionins in light of evidence provided by Oita et al defining alpha and beta thionins to contain 8 residues of Cysteine (see page 958, col. 1, first paragraph after abstract).

The concentration of NaCl is 500 times greater (50 mM) than the EDTA concentration (0.1mM) thus defining the solution by the component parts. The solutions comprises at least 4 sodium (Na+) ions for each EDTA molecule.

The reference inherently anticipates the instantly claimed compositions.

***Claim Rejections - 35 USC § 103***

6. Claims 1,4-8,22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al (WO96/41608). in view of Cutler (US Pat. 6,114,387).

See discussion of Vernon et al above. Vernon et al show the production of pharmaceutical compositions, that comprise the chelator EDTA, wherein the chelator is utilized in the formulation of a pharmaceutical composition, the EDTA being 0.1 mM EDTA (see Example 7, page 26), but differs from the instantly claimed invention by failing show or teach disodium or tetra sodium EDTA.

Cutler teaches EDTA to be commercially available as the free acid and as various salts, to include disodium EDTA and tetra sodium EDTA in an analogous art for the purpose of formulating pharmaceutical compositions that comprise chelators that are safe for industrial and human applications (see col. 1, lines 10-39), the formulations comprising low dosages of the chelators (see col. 1, lines 49-59).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the composition of Vernon et al that comprises EDTA, with the disodium or tetra sodium EDTA of Cutler because both Vernon et al and Cutler are directed to the formulation of pharmaceutical compositions and Cutler teaches the various salts of EDTA

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are commercially available, safe for human and industrial applications and readily incorporated into pharmaceutical compositions with one or more chelators and/or additional ingredients (see col. 1, lines 49-59).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of utilizing a disodium or tetra sodium EDTA in the place the EDTA of Vernon et al because the various salts of EDTA are well known and widely used (see col. 1, line 20) in the formulation of pharmaceutical compositions and are readily combinable into compositions for medical, industrial and commercial purposes (see col. 1, lines 30-67). Vernon et al in view of Cutler obviate the instantly claimed invention.

### **Conclusion**

7. **This is a non-final action.**

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. US Pat. 4,771,036 (Pigiet et al) is cited to show compositions that comprise purothionins from seeds (see col. 3, lines 55-61) of a 0.01 to about 10 mM concentration (see col. 4, line 17 together with 0.1mM EDTA (purification process, Example 2, line 27).

10. US Pat 5519115 is cited to show compositions of thionins together with 2 mM EDTA (see Detailed description of enriched chloroplast fraction buffer contains 2mM sodium EDTA).

11. US Pat. 6,329,011 is cited to show thionin compositions.

12. US Pat. 6,653,463 is cited to show a thionin in 1mM EDTA (see column 11, lines 12-63; col. 8, lines 29-48; cols. 13-14 Results and col. 16, lines 41-44).

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13. EP 0502718 is cited to show compositions of alpha and beta type thionins (see claims 2-28, pages 19-20) used against pathogenic microorganisms, the compositions together with one of a number of known carriers and buffer agents (see page 7, lines 15-30).
14. WO93/05153 is cited to show anti-bacterial proteins (see abstract).
15. Almeida et al (2000) is cited to show a plant defensin (150 ug) in 1 mM EDTA (see page 279, col. 2, paragraph 4).
16. Oita et al (2000), is cited to show thionins.
17. Terras et al (1993) is cited to show CaCl<sub>2</sub> to abolish the anti-bacterial activity of a thionin (see page 1315, col. 2, paragraph 2).

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp

March 1, 2005

  
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